K030683

10/31/03

NIPRO MEDICAL CORPORATION
3150 N.W. 107 Avenue
Miami, Florida 33172
Tel.: (305) 599-7174
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SUMMARY OF SAFETY AND EFFECTIVENESS
NIPRO DISPOSABLE SYRINGES

§807.92 (a)(1)

Contact Person: Cary Goldsmith
Product Manager

Date of Summary Preparation: March 4, 2003

5807.92 (a)(2)

Trade Name: Nipro® Disposable Syringes
Common Name: Sterile Disposable Syringe with/without needle
Classification Name: Piston Syringe, Hypodermic Single Lumen Syringe ($880.5860)

§807.92 (a)(3)

Legally Marketed Substantially Equivalent Device:
Nipro Branded Disposable Syringes (K944355)

S807.92 (a)(4)

Description of Device:

The subject devices can be classified as piston syringes as described in 21 CFR 880.5860. Among the syringe types described here are: flat-head; circular irrigation syringes; and, screw nozzle syringes. Various sizes are described including: 1, 2, 2.5, 3, 5, 10, 20, 30, 50, and 100 milliliters.

9807.92 (a)(5)

Intended Use: The Nipro® Disposable Syringes are intended for use to inject fluids into or withdraw fluids from the body.

9807.92 (a)(6)

Comparison of Technical Characteristics:

The Nipro subject and predicate devices are very similar in materials, design and technological characteristics. Performance tests demonstrated that the devices are substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 31 2003

Nipro Medical Corporation
C/O Ms. Kaelyn B. Hadley
Consultant
Kaelyn B. Hadley
1384 Copperfield Court
Lexington, Kentucky 40514-1268

Re: K030683
Trade/Device Name: Nipro Disposable Syringes
Regulation Number: 880.5860
Regulation Name: Piston Syringe
Regulatory Class: II
Product Code: FMF
Dated: September 22,2003
Received: September 23,2003

Dear Ms. Hadley:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

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Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 **CFR** 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4618. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Chiu Lin, Ph. .
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indications for Use Statement

510(k) number (if known): K030683

Device name: Nipro® Disposable Syringes

Indications for use: The Nipro® Disposable Syringes are intended for use to inject fluids into or withdraw fluids from the body.

Patricia Cucenta

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K030683

(Do not write below this line- continue on another page if needed.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The- Counter-Use ——
(Per 21 CFR 801.109) (optional Format 1-2-9)